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| 09/754,733      | 01/04/2001  | Gary K. Michelson    | 101.0056-09000      | 4482             |

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CHANTILLY, VA 201511101

EXAMINER

REIP, DAVID OWEN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3731

DATE MAILED: 12/05/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/754,733

Applicant(s)

MICHELSON, GARY K.

Examiner

David O. Reip

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.C. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 26,36,37,51 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,13-25,27-35,38-50,52-75 and 77-101 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(a) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Species 1 in Paper No. 8 is acknowledged.

Claims 36, 37, and 76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8. Additionally, claims 26 and 51 are withdrawn from further consideration as being drawn to nonelected species of invention, since elected Species 1 does not include a slot along the longitudinal axis of the plate.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 44, 70, and 97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is first noted that the claimed material "polygyconate" appears to be in error, since there is no such substance. The examiner has assumed the applicant wishes to claim the material as polyglyconate, which is a

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known absorbable polymer. However, the specification seems to be lacking any specific reference to polyglyconate. Therefore, claims directed to polyglyconate are not enabled.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 21, 24, 25, 27-29, 55-60, 72, 75, 77-87, 90, 93, and 99 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yapp et al (U.S. Pat. No. 5,549,612. Figs. 1-5 and the disclosure in col. 5, lines 27-37 clearly show an anterior cervical plate having all the limitations as recited in the above listed claims, including: a plate 12 having a rectangular configuration with "lobes" and a complex curvature with radii of curvature as claimed, the plate further having bone screw holes 19,20 and a "roughened" bone-contacting surface 18; and bone screws 14.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-20, 22, 23, 30-35, 38-50, 52-54, 61-71, 73, 74, 88, 89, 91, 92, 94-98, 100, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yapp et al. As previously discussed, Yapp et al shows an anterior cervical plate which is basically the same as that recited in claims 14-20, 22, 23, 30-35, 38-50, 52-54, 61-71, 73, 74, 88, 89, 91, 92, 94-98, 100, and 101. However, Yapp et al does not specifically disclose: bone growth promotion substances and resorbable materials (ref. Claims 14-20, 22, 23, etc.); and the central longitudinal axes of the bone screw receiving holes forming an included angle to each other in the range of approximately 15-30 degrees (ref. Claims 30-34, etc.) With respect to bone growth promotion substances, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use such substances with the Yapp et al plate to enhance bone growth, ingrowth, and fusion, since such substances are well known in the art and are commonly used to promote bone fusion. Likewise, it would have been obvious to one of ordinary skill in the art to make the Yapp et al plate of resorbable material to preclude the possibility of having to remove a non-resorbable (e.g. titanium) plate post-fusion. Further, with

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respect to the central longitudinal axes of the bone screw receiving holes forming an included angle to each other in the range of approximately 15-30 degrees, it is noted that although Yapp et al is silent as to said angle, such appears to be inherent or at least would have obvious to the skilled artisan.

Claims 8-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yapp et al in view of Lowery et al (U.S. Pat. No. 5,364,399). As previously discussed, Yapp et al shows a cervical plate which is basically the same as that recited in claims 8-10 and 13, including wherein the screw have heads dimensioned to achieve an interference fit (ref. Cl. 9) and wherein the bone screws are convergent (ref. Cl. 13). However, Yapp et al does not specifically disclose each of the bone screws being retainable in a respective one of the bone screw receiving holes below the upper surface of the plate (ref. Cl. 8), and self-tapping screws (ref. Cl. 10). Lowery et al teaches a cervical plating system having screws which are retained within their respective bone screw receiving holes below the upper surface plate. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reduce the depth dimension of the screw heads of Yapp et al so as to allow the screws to be retained below the plate surface in order to present the lowest possible profile plate system, which advantageously helps minimize soft tissue damage in a patient. Additionally, with respect to claim 10, self-tapping screws are well known in the art since they allow screw placement without the additional time and risk associated with drilling holes in vertebrae.

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***Allowable Subject Matter***

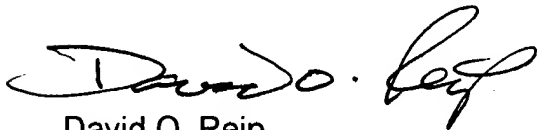
Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Claim 11 contains allowable subject matter because the prior art fails to disclose or suggest a cervical plate system having all the limitations as recited in base claim 1 and intervening claim 8, and including a bone screw having a structure as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip at (703) 308-3383. The examiner can normally be reached Mon-Thu and every other Fri from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Recla, can be reached at (703) 308-1382. The fax number for this Unit is (703) 308-2708 (unofficial) or (703) 305-3590 (official).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858.



David O. Reip  
Primary Examiner  
November 29, 2001